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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,780	11/17/2000	Helene Gras-Masse	1091/2 PCT/US	9478

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10/03/2003

Irving N Feit
Hoffmann & Baron
6900 Jericho Turnpike
Syosset, NY 11791

EXAMINER

FOLEY, SHANON A

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 10/03/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/555,780

Applicant(s)

GRAS-MASSE ET AL.

Examiner

Shanon Foley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-11 and 13-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant timely responded to the first action on the merits of July 5, 2001. However, due to inadvertent clerical errors, the Office has not timely responded to applicant's amendment submitted December 4, 2001. The examiner regrets any inconvenience applicant experiences due to this delay.

In paper no. 15, applicant amended claims 1-6, 9-11, 13-16, 18-20, 22 and added new claim 25. Claims 1-25 are pending. Claims 8 and 12 are withdrawn from consideration due to a non-elected invention. Claims 1-7, 9-11 and 13-25 are under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 9-11 and 13-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims have been amended to state that each of the micelles comprise the first and second lipopeptide. Applicant has not pointed to support for where this limitation can be found and the examiner is unable to locate support. Applicant is required to point to support for the limitation or cancel the new matter.

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Claims 13, 14, 16 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for reasons of record.

Applicant submits and summarizes two journal articles that demonstrate effectiveness of the claimed vaccine compositions. Applicant argues that the data from these journals indicate the instant vaccine's effectiveness. Applicant also argues that the examiner has not presented evidence that the instant vaccine would be ineffective.

Applicant's arguments and the journal articles have been fully considered, but are found unpersuasive. Although Pialoux et al. and Gahery-Seard et al. demonstrate a CTL response is induced, the references offer insufficient data to obviate the rejection of record. There is no data that would indicate that the instant vaccine composition has therapeutic and/or prophylactic efficacy in HIV-infected subjects. The claims assert therapeutic and protective efficacy of the instant composition, but invite the skilled artisan to prove the vaccine's effectiveness. Applicant has provided no working example or data that would indicate that a vaccine against HIV has been demonstrated. There is no known HIV vaccine known in the art and the predictability for such a vaccine is extremely low. Therefore, applicant is required to submit sufficient data that would indicate that the composition is efficacious within the HIV vaccine art. The articles submitted by applicant do not alleviate previous grounds of rejection or known problems of developing and using an HIV vaccine. There is no data in the specification or the references that have been submitted that would indicate that an induced CTL response would be beneficial to

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HIV-infected individuals. Therefore, due to the lack of guidance in the application, the lack of working examples, and the nature of this invention, it is concluded that undue experimentation would be required of the skilled artisan to practice the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 9-10, 13-17, 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stuhler et al., Sastry et al. and Sugimoto et al. for reasons of record.

Applicant argues that the rejection is misplaced because the claims are not drawn to conjugating the CTL to the helper epitope by palmitic residues in the micelle or linked micelle epitopes.

Applicant's arguments have been fully considered, but are found unpersuasive. Although the claims do not recite the limitations discussed by applicant, the claims are interpreted within the broadest interpretation. Further, in response to applicant's argument that the concepts presented by the examiner is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the claims are drawn to micelles comprising at least one CTL epitope and a helper epitope and lipid units for each epitope in an immunogenic composition. Stuhler et

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al. teach CTL and helper epitopes and activating a number of immune cell types. Stuhler et al. do not teach Stuhler et al. does not teach palmitic acid residues, but Sastry et al. do. Moreover, Sastry et al. elicit cell-mediated immunity with micelle compositions comprising an HIV protein attached to palmitic acid residues.

One of ordinary skill in the art at the time the invention was made would have been motivated to combine the method of stimulating helper, CTL, and APC immune responses by combining the helper and CTL epitopes taught by Stuhler et al. in the micelle composition taught by Sastry et al. because the linked micelle epitopes would contact the same APC at the same time and the epitopes would not require a carrier molecule. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation in producing the claimed composition and specific immune response to HIV-gag because Stuhler et al. successfully stimulates all three cell types in an immune regulatory cluster to an HIV-gag peptide by stimulating the CTL and helper epitopes on one APC. Sastry et al. teaches a method of successfully stimulating an immune response to HIV-gag by combining the short peptide sequence in a micelle configuration. Therefore, the invention as a whole would have been prima facie obvious at the time the invention was made, absent unexpected results.

In conclusion, the claims recite a composition of micelles and what they contain. The combined teachings in the prior art teach all of the limitations in the claims, provide a motivation for combining the teaching with a more than reasonable expectation of success in producing the claimed invention. Therefore, it is determined that the teachings of the prior art is highly relevant to the subject matter of the instant claims.

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Applicant also argues that there is no motivation to combine the Stuhler et al. and Sastry et al. references. Applicant argues that Stuhler et al. provide no indication of the preferred mode of presentation of the antigenic determinants to the APCs. Applicant argues that Stuhler et al. merely teach that CTL and helper antigens are required to elicit a cytotoxic T cell response. Applicant further argues that Sastry et al. teach cytotoxic T cell response without an induction of an antibody response.

Applicant's arguments and a full review of the references have been considered, but are found unpersuasive. Stuhler et al. do not have to teach a preferred method of delivery because Sastry et al. do. The combined teachings of Stuhler et al. and Sastry et al. is drawn to a micelle comprising CTL and helper epitopes and palmitic acid structures that exposes and simultaneously stimulates APCs with different epitopes, that do not require the construction of a carrier molecule. This combination of teachings is accomplished with a reasonable expectation of success. Therefore, the invention as a whole is prima facie obvious to one of ordinary skill in the art, absent unexpected results to the contrary.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stuhler et al. and Sastry et al. and Sugimoto et al. as applied to claims 1-7, 9-10, 13-17, 19-24 above, and further in view of Kramer et al. for reasons of record.

Applicant argues that the teachings of Kramer et al. fail to remedy the defects of Stuhler et al., Sugimoto et al. and Sastry et al. However, there does not appear to be a defect in the combination of references cited above. Therefore, the invention as a whole is prima facie obvious to one of ordinary skill in the art for reasons of record.

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Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stuhler et al., Sastry et al., Sugimoto et al., and Kramer et al. as applied to claims 1-7, 9-11, 13-17, 19-24 above, and further in view of Shapiro et al. for reasons of record.

Applicant argues that the teachings of Shapiro et al et al. fail to remedy the defects of Stuhler et al., Sugimoto et al. and Sastry et al. However, there does not appear to be a defect in the combination of references cited above. Therefore, the invention as a whole is prima facie obvious to one of ordinary skill in the art for reasons of record.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Shanon Foley


JAMES HOUSEL 10/1/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600